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**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In Re Application of:

**Chien et al.**

Confirmation No.: **2874**

Serial No.: **10/048,191**

Art Unit: **1648**

Filing Date: **January 25, 2002**

Examiner: **MOSHER, M.**

Title: **HEPATITIS C VIRAL ANTIGEN IMMUNOASSAY DETECTION  
SYSTEMS**

**AMENDMENT UNDER 37 C.F.R. §1.312**

Mail Stop Issue Fee  
Commissioner for Patents  
PO Box 1450  
Alexandria, VA 22313-1450

Sir:

The following amendments are being submitted pursuant to 37 C.F.R. §1.312 with the payment of the issue fee.

Amendments to the claims begin on page 2 of this paper.

Remarks begin on page 6 of this paper.

Amendments

In the Claims:

The following listing reflects amendments to the claims and replaces all prior versions and listings of claims in this application.

1. (Currently amended) A method for detecting hepatitis C virus in a biological sample comprising the steps of:

contacting a biological sample suspected of containing hepatitis C virus with an ~~anti-human~~ anti-human antibody and at least one monoclonal anti-hepatitis C virus envelope protein antibody under conditions that allow an immunologic reaction between said antibodies and said sample; and

detecting the presence of immune complexes of said antibodies and said envelope protein, wherein detecting said immune complexes indicates the presence of hepatitis C virus.

2. (Original) The method of claim 1 wherein said anti-human antibody is attached to a solid phase.

3. (Original) The method of claim 2 wherein said solid phase is selected from the group consisting of microtiter plates, paramagnetic particles, and paramagnetic beads.

4. (Currently amended) The method of claim 1 wherein said monoclonal antibody reacts with an epitope selected from the group consisting of an e2 conformational epitope, an e2 linear epitope, an e2 linear neutralizing epitope, an ~~e1~~ e1 conformational epitope, an ~~e1~~ e1 linear epitope, and an ~~e1~~ e1 linear neutralizing epitope.

5. (Currently amended) The method of claim 1 wherein said at least one monoclonal antibody reacts with an e2 conformational epitope, an e2 linear epitope, an e2 linear neutralizing epitope, an ~~e1~~ e1 conformational epitope, an ~~e1~~ e1 linear epitope, an ~~e1~~ e1 linear neutralizing epitope, or a combination thereof.

6. (Original) The method of claim 1 wherein monoclonal antibody is detectably labeled.

7. (Original) The method of claim 1 wherein said anti-human antibody is contacted with a polyclonal anti-hepatitis C virus envelope protein antibody prior to contact with a biological sample.

8. (Currently amended) A method for detecting hepatitis C virus in a biological sample comprising:

contacting an anti-human antibody attached to a solid phase with a polyclonal anti-hepatitis C virus envelope protein antibody;

contacting a biological sample suspected of containing hepatitis C virus to said polyclonal antibody;

contacting said sample with at least one detectably-labeled, monoclonal anti-hepatitis C virus envelope protein antibody under conditions that allow an immunologic reaction between said antibodies and said sample; and

detecting the presence of immune complexes of said antibodies and said envelope protein, wherein detecting said immune complexes indicates the presence of hepatitis C virus.

9. (Original) A method of screening blood components or blood for hepatitis C virus prior to the use of such blood or blood component to prepare blood products comprising:

reacting a body component from a potential donor with an anti-human antibody and at least one monoclonal anti-hepatitis C virus envelope protein antibody under conditions that allow an immunologic reaction between said antibodies and said body component;

detecting the presence of immune complexes formed between said antibodies and hepatitis C virus envelope proteins; and

discarding any blood or blood component from said donor if said complexes are detected.

10. (Currently amended) A kit for detecting hepatitis C virus in a biological sample comprising:

an anti-human antibody;

at least one monoclonal ~~anti-hepatitis~~ anti-hepatitis C virus envelope protein antibody;

control standards; and

instructions for use of the kit components.

11. (Original) The kit of claim 10 further comprising a polyclonal anti-hepatitis C virus envelope protein antibody.

12. (Original) The kit of claim 10 wherein said anti-human antibody is attached to a solid phase.

13. (Currently amended) The kit of claim 10 wherein said monoclonal antibody reacts with an epitope selected from the group consisting of an e2 conformational epitope, an e2 linear epitope, an e2 linear neutralizing epitope, an ~~e1~~ e1 conformational epitope, an ~~e1~~ e1 linear epitope, and an ~~e1~~ e1 linear neutralizing epitope.

14. (Currently amended) The kit of claim 10 comprising a plurality of monoclonal antibodies which react with an e2 conformational epitope, an e2 linear epitope, an e2 linear neutralizing epitope, an ~~e1~~ e1 conformational epitope, an ~~e1~~ e1 linear epitope, an ~~e1~~ e1 linear neutralizing epitope, or a combination thereof.

15. (Original) The kit of claim 10 wherein said monoclonal antibody is detectably labeled.

Remarks

The foregoing amendments are being made to correct typographical errors introduced via the Examiner's Amendment. In particular, applicants have inserted hyphens that were inadvertently dropped by the Examiner and have changed el to "el." The substance of the claims remains the same. Accordingly, entry of the amendments is respectfully requested.

Respectfully submitted,

Date: March 17, 2004

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